

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

One Montvale Avenue
Stoneham, MA 02180
(781)587-7500 Fax: (781)587-7556

DATE(S) OF INSPECTION

2/10/2016-2/26/2016*

FEI NUMBER

3001451521

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Brian Corbley , Facility Team Leader

FIRM NAME

Whole Foods Market North Atlantic
Kitchen

STREET ADDRESS

9 Commercial St, Suite 300

CITY, STATE, ZIP CODE, COUNTRY

Everett, MA 02149-5506

TYPE ESTABLISHMENT INSPECTED

Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Failure to manufacture , package and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

Specifically, on 2/10/16, 2/16/16 and 2/18/16 the following conditions and practices were observed in the Assembly Room (K4), K8/K9 Room, Veg Prep Room, Pre-Pack Room and Bulk Room:

- A. On 2/10/16, you were mixing RTE pesto pasta directly under an area in the Assembly Room (K4) where condensate from ceiling joints was dripping on the surface below.
- B. On 2/16/16, you were holding an uncovered rack of RTE mushroom quesadilla in the same area of the Assembly Room (K4) where condensate from ceiling joints was dripping on the surface below.
- C. On 2/10/16, you were transporting uncovered RTE vegetables through a doorway above which significant condensate had formed and was dripping. The doorway led to the Prepared Veg Cooler from the Veg Prep Room.
- D. On 2/10/16, you were cutting chives and beets on a work surface directly under a leaking condensate drainage pipe in the Veg Prep Room.
- E. On 2/16/16, you were holding uncovered RTE egg salad in large white barrels that were placed in an area below the condenser that dripped approximately once per second from the condenser fan bolts in the K8/K9 Room.

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Rupa Pradhan, Investigator
John L Zacccone, Investigator

2/26/2016

DATE ISSUED
2/26/2016

X Rupa Pradhan
Rupa Pradhan
Investigator
Signed by: Rupa Pradhan - 5

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- F. On 2/16/16, you were transporting uncovered RTE couscous through an area in K8/K9 where condensate was dripping from an area around the fan bolt at approximately once per second.
- G. On 2/10/16, 2/16/16, 2/18/16, you were holding RTE vegetables, utensils such as cutting boards, mandolins, stainless colanders and yellow plastic totes in close proximity to hand washing station in the Veg Prep Room. The hand washing station does not have splash guards and is foot operated releasing water from the faucets with significant pressure causing water to splash outside the sink while washing soiled hands. Water was splashing onto covered and uncovered vegetables as well as utensils and food containers.
- H. On 2/16/16, you measured the strength of peracetic acid from the faucet in the Veg Prep Room with an (b) (4) Peracetic Acid that indicated its strength over 160 ppm (maximum level on the test strip). This concentration exceeds the maximum level recommended by (b) (4) product information sheet and the maximum level allowed under 21 CFR Part 173.315(a) (5) for use of peracetic acid for surface treatment and soaking and rinsing of vegetables.
- I. On 2/16/16, your employee was performing multiple tasks in the Pre-Pack Room such as filling and weighing RTE egg salad onto retail packs, directly touching product and cleaning work surfaces without hand washing or changing gloves in between tasks.
- J. On 2/16/16, your employee performing multiple tasks in the Bulk-Pack Room when packing RTE quinoa cakes and assembling bulk cartons without hand washing or changing gloves in between tasks.
- K. On 2/16/16, your employee in the Pre-Pack Room was spraying (b) (4) quaternary ammonium based sanitizer to clean the work surface while another employee in close proximity was packing RTE mesclun salad. This resulted in sanitizer being sprayed onto an open colander of salad

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Rupa Pradhan, Investigator
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2/26/2016

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X Rupa Pradhan
Investigator
Signed by: Rupa Pradhan-G

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leafy greens.

- L. On 2/16/16, your employee's unprotected upper sleeves were frequently touching RTE leafy salad greens as they were assembling leafy salad greens into retail packs in the Pre-Pack Room.

OBSERVATION 2

Failure to maintain equipment in an acceptable condition through appropriate cleaning and sanitizing.

Specifically, the presence of non-pathogenic bacteria *Listeria welshimeri* was found on the environmental swab collected from the internal rotating drum portion of the (b) (4) machine (vegetable chopping) located in the Veg Prep Room on 2/10/16 at 12:07 PM. The presence of non-pathogenic bacteria *Listeria welshimeri* is indicative of failure to maintain food contact surfaces of equipment in an acceptable condition through appropriate cleaning and sanitizing. See Observation # 4-A, 4-B for cleaning and sanitizing of equipment.

OBSERVATION 3

Failure to sanitize and thoroughly dry, prior to use, food-contact surfaces which have been wet cleaned.

Specifically,

- A M. On 2/16/16, you had filled the dip tank for soaking sheet pans (used for raw meats and RTE in process and finished products) with a sanitizing agent (b) (4) quaternary ammonium based sanitizer. You measured the sanitizer strength using a color based (b) (4) Test strip which indicated the sanitizer strength of 100ppm. This strength is not adequate for sanitizing food contact surfaces as per the recommended limit identified as 200-400ppm by the manufacturer.

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Rupa Pradhan, Investigator
John L Zacccone, Investigator

2/26/2016

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Investigator
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B.N. On 2/16/16, you measured the sanitizer strength on the spray nozzle located in the dish washing room that is used for filling dip tank and for sanitizing larger portable equipment and parts such as rotating blades of (b) (4) machine and Ribbon Blender parts. The color based (b) (4) Test strip indicated sanitizer strength of 100ppm. This strength is not adequate for sanitizing food contact surfaces as per the recommended limit identified as 200-400ppm by the manufacturer.

e.S. On 2/16/16, you did not clean and sanitize the semi-permanent divider curtain in the K8/K9 Room after using high pressure spray hose to clean and sanitize the ribbon blender and the walls and floors surrounding the ribbon blender.

D.P. On 2/10/16, you were storing various utensils and equipment parts inside containers and on rolling carts that had pooling water.

OBSERVATION 4

Proper precautions to protect food and food-contact surfaces from contamination with chemicals, filth and extraneous material cannot be taken because of deficiencies in plant design.

Specifically, on 2/10, 2/11, 2/16 and 2/18/16 the following conditions were observed:

- A. You are using portable divider curtains and semi-permanent divider curtains to segregate areas between dishwashing room entrance and exit doors and the Assembly Room (K4) to keep soiled

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Rupa Pradhan, Investigator
John L Zacccone, Investigator

2/26/2016

DATE ISSUED

2/26/2016

X Rupa Pradhan
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dishes separate from the RTE products assembled and in the Assembly Room (K4). However, soiled equipment from various preparation processes including holding of raw chicken and turkey were touching both sides of the portable divider curtains. *See Observation # 4-C for cleaning and sanitation of these divider curtains.*

- B. You are using portable and semi-permanent divider curtains to segregate an area in the K8/K9 room when clean-in-place equipment such as ribbon blenders are cleaned and sanitized adjacent to an area where and when RTE foods are prepared. On 2/10/16 and 2/16/16, your use of high pressure hoses to clean the ribbon blender and the curtains were causing water and aerosolized spray from the cleaning activity to go beyond the portable divider curtains and semi-permanent divider curtains into areas where RTE food such as couscous and salad dressings were being prepared. Therefore, these portable and semi-permanent divider curtains do not provide adequate protection of RTE food when high pressure hoses are used to clean and sanitize clean-in-place equipment and the portable and semi-permanent divider curtains. Furthermore, these portable divider curtains do not have a designated clean and unclean side or a designated area of use. *See Observation # 4-C for cleaning and sanitation of these divider curtains.*
- C. On 2/10/16 and 2/16/16, soiled/unclean equipment had accumulated beyond the entrance of the dish washing room. Soiled/unclean equipment, utensils and food containers were being held beyond the portable divider curtains separating the dish washing room and the Assembly Area (K4). This resulted in soiled/unclean equipment to be held for indefinite period of time in close proximity to RTE preparation activities such as making of enchiladas, mixing of pesto pasta and quesadillas. The existing entry and exit doors of the dish washing room that opens into the busy Assembly Room (K4) where RTE products are prepared and the limited capacity of the dish washing room may contribute to this condition.

OBSERVATION 5

Hand-washing facilities lack running water of a suitable temperature.

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EMPLOYEE(S) SIGNATURE

Rupa Pradhan, Investigator
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3/24/2016

DATE ISSUED

2/26/2016

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Specifically, on 2/16/16 the hand washing station located at the entrance of the K8/K9 room did not have warm/hot water. Your employees returning from break and other non food related tasks continued to use this tagged "out of service, no hot water, 2/16/16" hand washing sink before returning to preparing and handling RTE products.

OBSERVATION 6

Failure to properly identify toxic sanitizing agents in a manner that protects against contamination of food.

Specifically, on 2/16/16 an unmarked drum of chemical that was connected to the vegetable preparation sink was observed in the Veg Prep Room. It was verbally identified as peracetic acid to be used to soak vegetables.

***DATES OF INSPECTION**

2/10/2016(Wed),2/11/2016(Thu),2/16/2016(Tue),2/18/2016(Thu),2/26/2016(Fri)

2/26/2016

X John L. Zacccone

John L. Zacccone

Investigator

Signed by: John Zacccone Jr -S

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Rupa Pradhan, Investigator
John L Zacccone, Investigator

DATE ISSUED

2/26/2016

X Rupa Pradhan

Rupa Pradhan

Investigator

Signed by: Rupa Pradhan -S

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."